REMARKS

In the Office Action dated December 23, 2008, claims 1, 8-22 and 29-45 were examined with the result that all claims were rejected. The Examiner made the rejection final. In response, Applicant has filed a Request for Continued Examination and via the present Amendment has cancelled claims 12-19 and 29-45, and amended claim 1. In view of the above amendments and following remarks, reconsideration of this application is requested.

Before turning to the rejections of record, Applicant would like to briefly summarize the amendment made to claim 1 via the present response. More specifically, claim 1 has been amended to now recite a method of improving bone quality following a distraction osteogenesis procedure by administering a therapeutically effective amount of a compound of the described Formula I. Thus, claim 1 has now been limited to improving bone quality following a distraction osteogenesis procedure, and presents no new matter as this use was specifically set forth in the second-last line of page 4 of the specification as filed.

In the Office Action, claims 1, 8-22 and 29-45 were provisionally rejected on the grounds of non-statutory obviousness type double patenting as being unpatentable over claims 1, 8-10, 20 and 29-38 of co-pending application no. 10/105,826. The Examiner indicated that although the claims are not identical, they are overlapping in scope and thus the Examiner concludes that the present claims and those in the '826 application are obvious variations of each other. This rejection is a provisional rejection because the allegedly conflicting claims in the two applications have not yet in fact been patented. As a result, Applicant respectfully requests the Examiner to hold this rejection in abeyance pending the resolution of all other issues surrounding this application and/or co-pending application 10/105,826.

In the Office Action, claims 29, 30, 33-35, 44 and 45 were rejected under 35 U.S.C. §103(a) as being unpatentable over DeLuca et al U.S. 5,843,928 in view of DeLuca et al WO 02/05823 and Bockman et al U.S. 5,556,645. However, Applicant has cancelled claims 29-45 via the present amendment and thus believes this rejection is now moot. Applicant requests the Examiner withdraw this rejection in response to the cancellation of those claims.

In the Office Action, claims 12-19 and 36-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over DeLuca et al U.S. 5,843,928 in view of DeLuca et al WO 97/11053. Again, however, Applicant has cancelled claims 12-19 and 36-43 in the present response. As such, Applicant believes this rejection is also now moot, and requests the Examiner withdraw this rejection in view of the cancellation of these claims.

In the Office Action, claims 1, 8-11 and 20-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over DeLuca et al U.S. 5,843,928. The Examiner states that one skilled in the art would readily envision utilizing a compound such as 2MD, which is disclosed in the '928 patent, to form new bone. However, the Applicant respectfully disagrees with the Examiner for the following reasons.

A close reading of the '928 patent reveals that the '928 patent does not state that the compound 2MD forms new bone. Instead, the '928 patent teaches that the compound 2MD can be utilized to treat diseases "where bone formation is desired." In other words, the phrase "where bone formation is desired" modifies the type of disease being treated so that, for example, osteoporosis, osteomalacia or renal osteodystrophy could be treated with the compound 2MD. Each of these diseases typically require that a compound would be effective to increase bone mass. However, increasing bone mass can be accomplished in different ways. For example, estrogens and bisphosphonates are known to increase bone mass by inhibiting bone calcium resorption. Neither of estrogens or bisphosphonates actually function to stimulate and form new bone, but instead function to turn off osteoclasts so that the resorption of calcium into the blood from bone is inhibited. As a result, since osteoclasts are inhibited and the osteoblast cells continue to form new bone, there is a net increase in bone mass.

If one looks at the biological data set forth in the '928 patent, one sees that the compound 2MD is characterized by little, if any, intestinal calcium transport activity but significantly high ability to mobilize calcium from bone. Thus, the compound 2MD is particularly useful in cases where increased bone calcium mobilization would be desired, e.g. low bone turnover osteoporosis. However, it is important to note that the '928 patent never states that the compound 2MD actually forms new bone by stimulating osteoblast cells.

In the present application, the inventors have found that surprisingly the 2-carbon modified vitamin D compounds of the claims markedly stimulate the growth of new bone when added to cultures of human bone-forming cells (osteoblasts). This finding indicates that these compounds can be useful in treatments such as improving bone quality following distraction osteogenesis procedures, such as now claimed. Such a treatment is a healing process that specifically requires the stimulation of new bone growth, and not only the stimulation of new bone growth, but the growth of new bone having the proper architecture. Just because new bone is formed, does not mean it will have the proper architecture. Merely increasing bone mass, as was indicated in the '928 patent, does not necessarily mean that the quality of bone produced is improved. Thus, to discover a compound or compounds that form new bone of the proper architecture by stimulating osteoblast cells is an important therapeutic remedy.

The prior art '928 reference merely states that the compounds disclosed therein may affect bone turnover, but do not teach or suggest that the compounds could actually stimulate growth of new bone. There is certainly no experimental data in the '928 patent which demonstrates this activity. Moreover, the general statements made therein about the potential uses of the compounds in relation to bone fracture healing, bone grafts, and knee and hip replacements would not have rendered the present claims obvious. This is because the '928 reference would not have provided the skilled person with any reasonable expectation that the compounds would be successful in treating a disease which requires the stimulation of new bone growth, as opposed to increased bone turnover. The prior art '928 patent may have suggested that the compounds could be used to increase bone mass, but it would not have suggested the new and non-obvious technical effect of the present invention, i.e. that the compounds markedly stimulate the growth of new bone, and that bone has the proper architecture following a distraction osteogenesis procedure.

In summary, Applicant submits that the present invention has demonstrated for the first time that the recited compounds are useful for stimulating osteoblasts to improve bone quality following a distraction osteogenesis procedure, which treatment is a healing process that specifically requires the stimulation of new bone growth. As stated above, the '928

reference makes no mention of the particular therapeutic application to which the claim is now limited and this use would therefore not have been obvious over the '928 reference.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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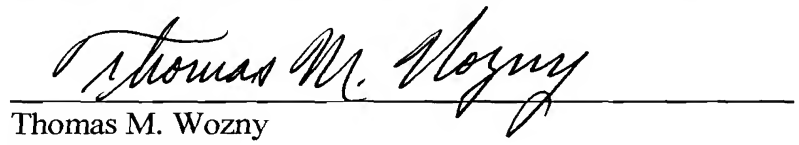

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